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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,374	12/20/2001	Brian J. Martinell	38-21(15347)C	4308

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,374

Applicant(s)

MARTINELL ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Status of the Claims

1. Claims 1-10 are pending and are examined in the instant case.

Specification

2. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1-10 are rejected under 35 USC § 112-2 for the following reasons

In claim 1,

- line 7, "under conditions in which" does not define the conditions, "wherein" is suggested,
- lines 9-10, "in a manner capable of identifying" does not teach what "manner" is appropriate. "to allow identification" is suggested.

In claim 4, "EPSP" is an abbreviation or an acronym. The full name should be spelled out at least once, preferably at the first recitation of the abbreviation. This should be followed by the abbreviation in parentheses.

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In claims 4 and 8, "further comprises" suggests that another sequence must be present in addition to the sequence in claims 3 and 7 respectively. It is suggested that the phrase "wherein the protein that confers glyphosate tolerance is an EPSP synthase protein" be used in claim 4 and "wherein the protein that confers kanamycin tolerance is a neomycin phosphotransferase (nptII)" is used in claim 8.

Corrections or clarifications are required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 2 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson, et. al., US 5,286,635.

Hanson teaches a method of transforming the embryonic axis of pea using an Agrobacterium vector (column 13, lines 33-49) , exposing the explant to a disarmed Agrobacterium containing a heterologous genetic construct (column 9, lines 36-41) where the exposing step to the Agrobacterium is within 14 hours of the initiation of germination step (column 9, lines 36-41), culturing in the presence of the selection agent kanamycin (column 5, lines 45-60) and transfer of herbicide resistance genes (column 5, lines 45-60).

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Hanson does not teach a method in soybean but in a garden pea (*Pisum sativum*), a closely related plant to soybean (*Glycine max*) in the Leguminaceae. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Hanson to transform soybean rather than pea. Both species have similar developmental processes and culture requirements and both are economically and agriculturally important crops.

7. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over Hanson, et. al., US 5,286,635 as applied to claims 1,2 and 7-9 above, and further in view of Barry et. al. (US 5,463,175 and 5,633,435) and Martinell et. al. (US 5, 914, 451).

The teachings of Hanson are discussed above. While Hanson does not teach the use of glyphosate as a selection marker or a method of shoot induction, Hanson does disclose the desirability of using "herbicide resistance" as a selectable trait.

Barry teaches the use of glyphosate tolerance in a transformed plant using a DNA coding sequence encoding the ESPS synthase protein where the protein is the CP4 protein (US 5,463,175, summary of the Invention, column 2 and 3; and US 5,633,435, column 11, lines 1-23). These references are included in applicant's admitted prior art (specification, p. 5, lines 33 bridging to p. 6, line 5).

Martinell teaches an *Agrobacterium* transformation method where glyphosate is used as a shoot inducing hormone and selection marker (column 4, lines 39-44).

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It would have been prima facie obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of Hanson to use glyphosate tolerance as applied by Barry or Martinell. The added effect, as taught by Martinell, of shoot stimulation by glyphosate makes it a very desirable selection characteristic. One would have a reasonable expectation of success because Barry and Martinell have successfully transformed plants using *Agrobacterium* mediated methods and incorporated glyphosate tolerance into plants, using this tolerance to induce shoot formation.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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9. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,384,301. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '301 claims are drawn to a method of making a germline-transformed soybean plants using Agrobacterium mediation comprising initiating the germination of a soybean seed, isolating the embryonic axis, *wounding the explant*, and exposing the explant to Agrobacterium.... The instant claims are drawn to method of making a germline-transformed soybean plants using Agrobacterium mediation comprising initiating the germination of a soybean seed, isolating the embryonic axis, and exposing the explant to Agrobacterium.... That is, the instant claims are silent as to the wounding the explant. However, the wounding process is inherently part of the process of preparing an explant, which is by definition an excised plant part. Alternatively, a separate wounding step would have been an obvious design choice, in absence of evidence to the contrary.

Remarks

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
Patent Examiner
Art Unit 1638
April 19, 2004



Amy Nelson
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